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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,597	10/12/2004	Joseph P. Errico	SPINE 3.0-437 CIPCIPCI	8309
51640	7590	11/06/2008	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
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			11/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,597	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimers filed on 8/7/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US PAT 7,223,291 and Appl. No. 10/663,488 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120 is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: no petition was filed with the late claim for priority. The Application was filed 2/23/04 and the amendment to correct the benefit claim was filed 10/6/05, which is 16 months late.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the *first sentence(s) of the specification* following the title or in an application data sheet during the proper time frame. For benefit claims under 35 U.S.C. 120, the reference must include the proper relationship (i.e., continuation, divisional, or continuation-in-part) of the applications desired to claim priority during the permitted time frame for submitting the claim to priority. Additionally, the reference to add the above, noted, prior-filed applications in the first sentence of the specification on page

one following the title is not acceptable as drafted since it has improperly incorporated by reference the prior-filed applications. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. § 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. § 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. § 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Industries v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). Note MPEP §§ 201.06(c) and 608.04(b).

Thus, since the instant application is a utility application filed under 35 U.S.C. 111(a) after November 29, 2000, the specific reference must be submitted during the pendency of the application and *within the later of **four months** from the actual filing date of the application* or sixteen months from the filing date of the prior application. This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). *A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c).* The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to

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the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 18, the limitation that the holes would be perpendicular to “a *surgical approach direction*” in line 13 of the claims is indefinite in that this provides no specific frame of reference for any person of skill in the art to know where this “direction” is coming from. The term “approach” can be interpreted to mean coming near something and thus provides no clear definition to the surgical technique. The term “direction” is a broad term with numerous possibilities to define where some surgeon might be working from. Thus since no definite orientation can be ascertained from the terms used, it is indefinite. The remaining claims depend from these two claims and are indefinite for this reason.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3,5-7,10-12,18,19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ralph et al. (6471725).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131. Fig. 1b illustrates apparatus **100** to prepare an intervertebral space for implantation of an artificial intervertebral disc with baseplates **104**, **106** having a plurality of engagement holes on the baseplates. The apparatus also includes a trunk **103** which is cylindrical with an annular groove **102** about it.

Claims 1,3-7,10-12,14,18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Paponneau (2003/176925). Fig. 1 shows apparatus for preparing an intervertebral space with two baseplates **24**, **26** and are immovably coupled via

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cylindrical trunk **22**. Fig. 2 shows clips to "immovably couple" the plates together. Fig. 3 show the baseplates include a plurality of engagement holes **64A-C**, **66A-C** extending into the baseplate to a direction substantially perpendicular to the plurality of surgical approach directions. Regarding claim 4, Fig. 8A illustrates the plates can be angled with respect to one another and can be approximately 15 degrees. Regarding claims 6,7, since there is space about the trunk because it is smaller in width than the plates it forms a "groove" and is thus annular. With respect to claims 10,11, the apparatus is fully capable of being used in any of the surgical approach directions, such as an anterior or anterior-lateral approach. Regarding claims 12,14,20 since the baseplates have a thickness, it can be said that there is a surface facing an anterior surgical approach direction and two anterior-laterally facing surfaces extending perpendicular to the anterior-lateral approach.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Kuras (6607558). Paponneau is explained supra. However, Paponneau fails to disclose the contour of the outward facing surface of the baseplates to have a contour of a dome. Kuras teaches (Figs. 1-3) a spinal device that

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has two upper and lower support structures **20**, **40** with convex or domed outward facing surfaces **22**, **42** for engaging the disc space. It would have been obvious to one of ordinary skill in the art to use a convex or domed contour as taught by Kuras for the baseplates of Paponneau such that it more closely matches the contour of the vertebrae surface that the apparatus is to engage.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Baumgartner (5370697). Paponneau is explained supra. However, Paponneau fails to disclose the floor of the groove is narrower than an opening of the groove or the groove floor being ridged. Baumgartner teaches (Fig. 1a) a spinal device that has two upper and lower support structures **2**, **3** with an inner “groove” having a floors with ridge **21** for holding the trunk component **5**. Baumgartner additionally teaches (col. 2, line 58) a narrower profile for the floor of the “groove”. It would have been obvious to one of ordinary skill in the art to modify the baseplates and use a ridged floor as taught by Baumgartner in the baseplates of Paponneau such that it more effectively retains the trunk between the two baseplates.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Berry (5895428). Paponneau is explained supra. However, Paponneau fails to disclose the anterior facing surface of the baseplates is angled at a degree of approximately 33.4. Berry teaches (Figs. 2,4) a baseplate that has an angled anterior facing surface. However, Berry does not teach the explicit angle. It would have been obvious to one of ordinary skill in the art to modify the anterior facing

surface to be angled as taught by Berry on the baseplates of Paponneau such that it provides more stability in the central region of the apparatus containing the trunk.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Nishijima et al. (5899941). Paponneau is explained supra. However, Paponneau fails to disclose the apparatus baseplates having different width and depth dimensions. Nishijima et al. teach (Figs. 3a,3b) apparatus for a spinal disc space with the upper and lower baseplates **2, 3** with different width and depth dimensions. Nishijima also teaches that one of the baseplates is to have the central structure integral with the plate, col. 1, lines 51-53. It would have been obvious to one of ordinary skill in the art to simplify the apparatus for the spinal space by making an integral trunk with the baseplate as taught by Nishijima et al. for the apparatus of Paponneau such that it reduces the cost of manufacturing by lowering the number of components that would have to be molded.

Regarding claims 16,17 it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a width having a range between 35-40mm, or use a depth having a range between 14-18mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Double Patenting

Applicant is advised that should claim 14 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738